Percutaneous Coronary Intervention Advisory Oversight Committee Meeting
June 23, 2011, Sacramento, California
09:30 a.m. to 2:30 p.m.

Attendance

Members Anthony Way, MD, Chair; Stephen Arnold, MD; Ralph Brindis, MD; George Fehrenbacher, MD; William French, MD; Steven Forman, MD; Dipti Itchhaporia, MD; Aditya Jain, MD; Sushil Karmarkar, MD; George Smith, MD; Rohit Sundrani, MD

UC Davis Melanie Aryana, MD; William Bommer, MD; Zhongmin Li, PhD; Geeta Mahendra, Laurie Vazquez, ANP

Facilitators Sheila Fleege; Teresa Fleege

Agenda Items/Discussion	Action/Follow-up
Call to Order and Introductions: PCI AOC Chair Anthony Way (Chair) convened the meeting with introductions in the room and on the conference line. Special introduction of Carrie Camarena, Senior Counsel with DPH in the Licensing and Certification Dept. She has been asked to assist Dr. Way and the committee with legal issues. Background: With DPH for four years, prior litigator for public defender in the Bay Area. Graduate of UC Davis Law School. **Approval of Minutes:** • No Changes **Motion to approve January 20, 2011 as written** ➢ Motion— Fehrenbacher ➢ Second—Brindis ➢ Motion passed as written by unanimous vote **Public Comment** • None	
Old Business No discussion of old business from the field	
University of California, Davis Bommer – Welcome remarks. He mentioned a white and black	

copy of the PowerPoint presentation were also distributed. Will refer to the number on page so as to not get lost during discussion.

Way – On the white PowerPoint presentation copy the x-rays do not appear.

Bommer – Ok, we will use the black copy.

Karmarkar – Monitored is misspelled on every slide

Bommer – Recognition of UC Davis employees as a way of reward for their hard work. Laurie Vazquez, Auditor; Dr. Melanie Aryana, Dr. Zhongmin Li, Geeta Mahendra.

Thanks and congratulations to the interventionalists for their long hours of dedication taking care of very sick patients in addition to their regular schedules. Acknowledged Drs. Fehrenbacher, Arnold, Karmarkar and Forman.

Thanks to the coders who sit down with all the data and encapsulate the material into a computer website. Recognized were Patrick, Cardenas, Selda and Heist (Cath Lab manager)

Enrollment Update

Bommer – The five month data is audited, adjudicated, and reviewed, is "locked down" and will not change. Reviewed the enrollment of STEMI, NON-STEMI, Unstable Angina, Stable Angina, no symptoms; no angina, for a total of almost 500 patients. The second five month data not totally audited yet, up to June 1, doubled enrollment to 1,039. Continuing at same rate as first five months, on average of about 100 per month.

Brindis – – Maybe you want to go back to that slide. I had the data on the last 500,000 PCIs for the United States through the NCDR had a paper being presented next week and 21% are STEMIs, 20% NSTEMIs, 29% high risk/unstable anginas, 29% are non-acute. So, I found this fascinating which you and I would all expect to have a higher STEMI population. But, nevertheless, it seems like a fairly good reflective makeup of the clinical presenting symptoms of what is going on in the NCDR.

Bommer – We have a higher STEMI population in PCI CAMPOS than the reported national averages. This is good as we are meeting one of the proposals or goals of the original study by having enriched STEMI therapy in California.

Bommer – Hospital enrollment ranges from hospitals that have been randomly numbered. For the ten months the hospitals range from over 300 PCIs to a low of 77. Red line represents if we maintained the 200 level. The bill states 200 per year/per hospital. Two sites over the line, three close to the line and one halfway to the line. Sites should do 200 PCIs to maintain quality. Hospital at 10 months of exposure. Hospital 1 – 318 (STEMIs 18.9%) Hospital 2 – 224 (STEMIs 38%) Hospital 3 – 134 (STEMIs 41.8%) Hospital 4 – 77 (STEMIs 24.7%) Hospital 5 – 131 (STEMIs 29.8%) Hospital 6 – 155 (STEMIs 62.6%) Bommer – Do we want to have public reporting, currently by randomized numbers? We can continue with the assigned number for each hospital or specify that hospital X is actually this hospital in the program. Karmarkar – Will we report numbers or outcomes? If the outcomes haven't been scrutinized and validated that may be misleading to consumers and the hospital may come out in a negative light. Bommer – It is up to the AOC to make recommendations to DPH and DPH will make the decision if we continue with random identification or we actually identify it. Smith – Favors not releasing hospital names with low numbers. Fehrenbacher – More than a year data and data should be verified. It may not be appropriate to release names in a pilot project. Way – Timeline for reporting the first year data to the State, according to Senate Bill 891 is January 2012. Jain – Suggests risk adjusted mortality STEMI versus other lower risk. Itchhaporia – Agrees with the two Georges. Examine data carefully and be cautious and digest before publishing. Original goal was to see if in a rural area where there was no surgical back up, could we perform PCIs. Sundrani – My understanding is, when the study is over the data will be available to the public to see which hospitals has what numbers. Is that correct?	

Bommer – The AOC can make a recommendation to DPH how to do that and DPH will confer with legal office to decide what requirements are and make a decision. It is not clear in the bill that we are supposed to identify which hospital participates, but we do have to report the data.

Sundrani – We should wait at least a year into the study to get enough numbers before we identify hospitals.

Brindis – Agrees with the Georges, we should keep the hospitals de-identified for a number of reasons. Public misinterpretation of the data, understanding of confidence intervals, benchmarking related to data with NCR data.

French – There is a random scattering from hospital to hospital. A goal of 200 may be far from accessible in some of these hospitals. If a hospital can't get to the number should they remain in the study?

Brindis – Further comments by Brindis sharing national numbers.

Karmarkar – If and when a decision is made for reporting data, I just want to make sure that it doesn't hurt recruitment for future patients, if the data becomes public.

Camarena - My concerns in disclosing hospital names is patient confidentiality. It may be better to keep the hospitals numbered than named.

Bommer – Hospitals will be reported in the OSHPD statue. You can identify the mortality for PCIs at these hospitals. It is risk adjusted and the numbers will available through the OSHPD website.

Bommer – I'll go through the six hospitals. Slides 9-14 include hospital result updates.

Website/Software Update

Bommer – Data lockdown for 2010 on the last day of May. This data will not change. There are updates the website and hospitals will be seeing a software update. Coders will be timed out on the system and they will have to log back in. They may hit any button to stop from losing the screen. It is a safety feature and will be available on July 1st.

Another update will allow coders and administrators to run data completeness and harvest from their own site. They can look at their own data for completeness and to see if there are markers where data is missing. The Administrators will be able to send data directly to the NCDR on their own.

On June 2 the server went down for about four hours and had to be rebooted. All software had to be reloaded and this is our only known down time in the last 10 months.

Bommer – I will go over what the process of adjudication requires (see flow chart on slide 19) and what the steps consist of for one patient. Every patient's data goes into an initial data audit. It initiates queries for anything missing and then it goes back to the site for changes. 10% of random cases are selected for an in-hospital audit and includes all complications and mortality. The complete process takes five months for validation before it goes into lock down.

Audits

Bommer – 208 onsite audits at hospitals.

Brindis – Question about audit numbers at individual hospitals. What was the final decision by the committee?

Bommer – On August 1 the numbers will be reported. Once the numbers are in we will know which hospital does not meet the requirements. We will increase the audits at the hospitals that underperform. 20 audits is the minimum at the hospitals for audits. Presently we have performed 20% at the participating hospitals.

Karmarkar – Refers to the minutes on page 8, decision was that 20 cases should be audited at each hospital.

Brindis – to Bommer: The auditing is an ongoing process. Does your staff decide to do X amount each month or every third month?

Bommer – The audit process is as follows. Each hospital enters the number of the case it performs. Bommer continues to explain how coders random process for auditing. Mentions in addition to random cases chosen, that cases that report mortality and complications will also be audited.

Brindis – Since there is consistency of enrollment over 10 months, have you thought of the concept of prospectively basing

the audits on rates of enrollment, as opposed to trying to do it retrospect which affects the lockdown issue you have? Bommer – It takes time to get the coder and others to get those initiated. We have to make an appointment to send the auditor down there. Part of the time commitment is not sitting around and waiting, we identify which numbers to audit ahead of time. Then the auditor goes down there, they have to have the coder available and access to the medical record file. Brindis – Maybe I wasn't clear, say you have a shortfall in hospitals four to eight then you would over audit the next year. Is there a mechanism you would feel comfortable to prospectively appreciate how you audit in an ongoing fashion? Bommer – Lets take hospital four, they have done 77. We were hoping the numbers would increase the number of audits and we would make that number. If we look at the current rate, we would have to make up four to five audits prior to August 1. We will meet a minimum of 20 for every hospital. We have over 1000 patients enrolled and have 208 audits on the books. Aryana – These audits are through today, we haven't included the rest that have been done or the ones we will do up to August 1. Explains audit schedule. Bommer – Discusses Angiographic Audit diagnosis including status, elective, urgent, emergent and salvage. Bommer – Discusses lesion complexities. Discusses differences between Non C Type A or B lesions or if it is a high risk C lesion. Reviews characteristics of C lesions. High risk C lesions carry a higher risk of complications. Explains NCDR data. Fehrenbacher – States that is the old classification system. Bommer – Explains the classification system is NCDR data set. Part of risk adjustment model, so we have kept it at this point in time. Bommer – Showed slide 23 AVI file live (myocardial bridging). Hospital reported a lesion in LAD, PCI performed and stent placed. We question the hospital finding and feel it is myocardial bridging and not a fixed atherosclerotic lesion. Invites experts at table for their opinion. Committee – Agrees with diagnosis of myocardial bridging.	

Bommer – We overruled the site and said it was Myocardial Bridging. Any comments from remote sites? Jayne – Appears a small caliber. French – We may need to audit more angiograms. Bommer – Reviewed slides 24-27 and reported that it was not coded PCI, we feel it should have been. Showed wire going through the vessel. May be a dissection. Vessel has not been opened up. Coded as an elective CABG appropriate at this point. Not entered as a PCI, or failure of PCI. Our Interventionalist felt it was a PCI. Aryana – Requested coders make the change, we got back to Interventionalist and he agreed. Fehrenbacher – Discussion of difference of opinion on types of lesions. If someone attempts a PCI and codes it as a non-attempt, is this something the AOC wants to frown on and look further? I put that on the table. French – Agrees with Fehrenbacher and there should be more audits. Jayne – Once you put the wire down and with the intention to treat, it should be called a PCI. Arnold – Begins discussion of why patient not coded as a PCI. Bommer – No devices listed and not coded as a PCI. We feel devices were used and a PCI was done. We got back to coders who talked to Interventionalist who agreed a PCI was done. We changed data to report the PCI was done. Reported as an unsuccessful PCI. Karmarkar – Attempt was made to do a PCI. Continues discussion of veracity of reporting. Sundrani – Was the intention not to report the PCI? Bommer – We work from a data set, if we disagree with that we get back to the hospital that we disagree with. If everyone agrees to the changes then it is adjudicated and the information is locked down. Sundrani – Make a motion, if any wires are across the balloon no matter what the clinical situation it should be reported.	

Brindis – Worries the reason that this case was audited because the patient died. This group should write a letter of concern to the hospital administrators about this particular case about how duplicitous coding occurred and that it interfered with the proper evaluation of the pilot program. I raise that question of duplicitous coding. Way – You have a motion and a concern. French – We shouldn't have a suspension of hospital until this is clarified. We have a much more serious issue here, this is inappropriate. Fehrenbacher and Forman – Agree with French Aryana - Read definition of PCI Bommer – Classified as a PCI and a failed PCI French – I motion to have all angioplasty attempts where a balloon is passed, be recognized as a PCI and be reported. Second – Brindis French – More discussion regarding suggestion to suspend hospital based on last 50 cases and 50 cases going forward and counseling the Interventionalist on coding. Brindis – We should send a reprimand letter to the hospital asking for a formal response before we censor or suspend the hospital. Sundrani – We don't know if this is a coding mistake, we don't know. We should send a letter; we need to know the response before we suspend the hospital. Bommer – I have no idea on intent. Data on the website reflected it was a PCI. We submitted our findings back to the hospital and after discussion with the Interventionalist they agreed with our findings. Fehrenbacher – More discussion requesting more data and a response from the hospital. Way – Extensive discussion, review of motion, identified who will receive letter.	

Motion – Fehrenbacher –coordinating center would send letter to hospital, copying administration, the quality department and the Interventionalist asking for a detailed explanation of this case and how it was coded the way it did prior to our review. We also want details, enter how case proceeded and details on death of the subject. The letter should come back to the AOC, letter send secured out to AOC member now. Is that going to be consistent with Bagley-Keene? Camarena – Raises legal question about confidentiality. Is there a feeling of ethical violation? Because this is a state board it requires certain process. However, I feel the letter most likely will be fine. Bommer – I would like to amend the motion that the lawyer for DPH writes the letter. Camarena – I can do it with help of members of the committee. Way – You have reviewed the motion, the second, extensive discussion. **Motion – Fehrenbacher – Coordinating center would send a letter to the hospital, copying administration, the quality department and the Interventionalist asking for a detailed explanation of this case and how it was coded the way it was prior to our review. We also want details entered how case proceeded and details on death of the subject. The letter should come back to the AOC, letter send secured out to AOC member now.** ➢ Second Brindis ➢ Vote Passed Unanimously. Motion passed Way – Motion Carries **Compassionate Use** Bommer – Slide 28 Compassionate use applies to the individuals who come in for a PCI in extreme high risk: coma, ventricular assist devise or under CPR at the start of procedure. Reviews slides of Massachusetts compassionate use outcomes. We do not have compassionate use in the current NCDR data set. If we introduce compassionate use into our data set will the interventionalist be more likely take a high risk patient that we couldn't previously risk adjust to the high mortality of 70% in compassionate use individuals? I open this to discussion.	

Reviewed compassionate use questions of the data set on website. Fehrenbacher – Can we retroact to previous patients. Bommer – We might, but we have to talk to the hospitals. Fehrenbacher – It would in actuality be only a few cases. We only have to look at the deaths. Bommer – We have to know how many were qualified for compassionate use and lived versus how many were compassionate use and died to come up with fraction. Fehrenbacher – As the primary investigator it would be very easy for me to identify them. I would spend an hour with a coder and have it done. I remember most all of the patients. You only have a few that survive. Brindis – One of the challenges here is, if we look at the safety and efficacy of the program, compare with benchmarking with national or California data, we increase the disparity between the "apples and oranges" because we don't have compassionate use in the NCDR. Bommer – We can code for both so it's "apples to apples". We can for just this committee, introduce compassionate use additional risk modeling. We will give you both risk adjusted mortality with and without compassionate use. Bommer – I can have this on the website July 1st and we can go through with that and that allows our audits to be prospective. The retrospective does become a problem because it's memory of cases and we can't go through the re-audit process without doubling our efforts. It will be easier to do this prospectively rather than retrospectively. We have to have a lot of coders going through this and do it scientifically. I would propose that it would be much easier to begin prospectively July 1st. I'm not sure the coders have the time to do it. Karmarkar – I agree. Doing this retrospectively may or may not be the best way. Brindis – I want to congratulate George on proposing this. I think this is advancement in ensuring the sickest patients get the care they deserve and taking out the risk of the operator in the hospitals. As George wisely points out, the pilot hospitals are the ones that are more likely to have these types of	

patients.

Motion – Brindis - I would propose we put in compassionate use in a prospective fashion.

- Second – Sundrani
- 9 votes for, 1 no, the motion passes

Way – So the motion carries 9 to 1.

Overall/Hospital-level Success Rate

Bommer – The first category is post procedure stenosis. You can see we're running 90% success rate in the PCI campus program for successfully opening those vessels. You can see these numbers have not really changed in the first 5 months or second 5 months. We have good success for post procedure for reducing the residual stenosis. Now we're going to talk a little bit about mortality. We're going to look at mortality for the 5 month PCI group and the entire 10 month of the trial. The second thing we're going to review is the PCI mortality for a similar but not identical time for the rest of the California patient discharge data set. Third, we'll discuss the caterpillar approach, old way and we'll introduce a new statistical way of doing it. What you'll see is the traditional analysis had a somewhat different slant on the success of the program than the new analysis. Now Dr. Li will review mortality statistics.

Li - Let's start with the basic statistics on slide 34. The number is slightly different compared to the very beginning of the presentation because this data is from June 6. Complete data entry is slightly under 1,000. We have locked down 497. However I have one case different patient admitted December 31 and procedure performed January 1. Then we have January 1st, 2011, we have 476. In the hospital we had 21 deaths grand mean 2.16 %. For the first five months, we had 10 deaths. At one hospital we had no deaths, but at another we had 22%. Here is the patient discharge data. We are trying to get a whole year for 2010, but we have not gotten the second half of the year. This is a volume transition. We have one hospital that only did the one case, but on the other hand we have another hospital that did 900 (Patient Discharge Data and not to the PCI CAMPOS data.) This is the hospital observed mortality for non-pilot hospitals. The mean is 2.04% for this year, but for 2009 we had 2.19% for two years which is very stable. At the last AOC meeting Dr. Karmarkar requested we compare the standing vs. non-standing ratio. The test compares our first five months locked down or the total ten months non-locked down data.

**Dr. Li continues with extensive statistical data. Refer to attached PowerPoint presentation for statistical data.*

Li- Requests input from committee on analysis.

Bommer – What we've introduced is a new analysis. It's a little more robust and a more statistical method for assessing it. The Funnel Method looks at the entire group. If we get the approval, we are intending to present the traditional and the Funnel Method System.

Brindis – I would like you to continue the work. I think it is added value.

Bommer – The best comparison we have with California is the PDD data set. There was no significant difference between the PCI campuses with the rest of California.

Sundrani – The final plot data looks pretty good, but the goal of the project was to compare it with the NCDR data and I am glad to be the pilot site and we will be measured on a different statistical model. But, the goal of the project is to compare the data with the other hospitals that have onsite surgery, which is the traditional statistical model.

Jain – Is the compassionate use at risk if this is mortality? How would this data look if we used that?

Bommer – We haven't introduced that yet, but when we do we can include it in our risk adjustment model for the PCI campus data, but it is currently not in their data set. As I alluded to earlier, we can prepare a comparison with compassionate use and with it excluded from the model.

Karmarkar – I think this is a good internal quality measure. I think we should continue to look at this, but at terms of reporting outside the AOC, I see little value.

LUNCH BREAK

Bommer – Before we go to the appropriateness criteria, there was a question from George Smith.

Smith – The question is, if the minimal number of 200 is mandated by the legislation or suggested?

Way – I have reviewed the bill with our legal counsel. What the

statute doesn't tell you is what year two means. It can be taken at the beginning, middle, or the end. So it is discretionary from that standpoint. You can have 200 but it could be by the end of year two. The statutes often are written by legislators with legal help, but they don't always get everything included. In addition, there is nothing said about year three. After that there are no requirements. I give that to you for what it's worth. Bommer – Senate bill number 891 requires that the hospital perform at least 36 primary PCIs annually and has the capacity to perform at least 200 primary and elective PCI procedures annually and by year two of participation in the pilot program actually performs 200 primary and elective procedure a year. Sundrani – I appreciate Dr. Bommer coming to our site and helping us. We have an issue about getting the volume ramped up. We are not getting SD elevations MIs from the ambulances. The patients are going to other hospitals, even if they wish to come to us. We weren't able to meet the 36 PCI per year, because those patients are not coming to us. The other three hospitals in town are taking these patients so it's hard for us to get the numbers we want. In the last couple months, we have almost doubled our volume. Arnold – If at the end of 14 months from now a facility has not reached 200 PCIs per year for the second year, the facility will no longer be a part of this study, is that what you're saying? Way – No, it means that year two begins August 1st of this year to August 1st and goes to August 1st of 2012. They will have to have 200 by then. Way – Anything is possible, but at the rate you're going I highly doubt that anyone will be deleted. Bommer – I think that what we were saying is, the minimum is 200 per year by year two. What is by year two? August 1st, the middle of the year, or the end of the year? The attorney states that's not clearly stated in the bill, so that the interpretation by DPH could be by year two could mean that end of year two that they could have 200 per year. Way – Our current interpretation is to make it as broad as possible to avoid any possible legal backlash. I'm speaking for Carrie as best as she told me. Bommer – Clarifies current hospitals numbers: I would say that there are two that are over the minimum number, there are	

three that are at that number, and one that is below. We are going to proceed now. At the last meeting we talked about adding some guidelines. This is current last quarter from NCDR: (STATISTICS)

**Dr. Bommer reviewed PCI Process metrics, utilization metrics, data quality metrics and process comparison metric. Please refer to PowerPoint presentation for statistical data.*

Bommer – I would like to bring up Dr. Arayana and have her go through numbers. If you have questions, she will have the answers because she compiles all the data for us.

Arayana - All data excludes patients with acute coronary syndrome. We have listed patients who received PCI for stable angina, had no symptoms, or no angina. We are within the 25th – 75th percentile of the NCDR data set of all the hospitals. Overall 89% of our study population that were discharged on aspirin that had no contraindication for aspirin. With this variable we are below the 25th – 75th percentile that the NCDR provides from their computation. We looked at the percentage of patients discharged on thienopyridine with no contraindication for therapy. These were only the patients who had the statin implementation during hospital admission. We are at a mean of 89%, again we are below the 25th – 75th percentile that the NCDR provides. Statin report was not able to be run due to not being able to combine statins and non-statins. If we could run the report we would probably be in the 25th – 75th of the NCDR data set.

**Reviewed statistics on PowerPoint slides 66-70*

Fehrenbacher – Discussion regarding acuity (transfusions).

Brindis – I would be very interested to see bleeding rate by hospital with use of direct thrombin inhibitors. In particular hospital 6.

Aryana – It includes all transfusions and if there is a GI bleed it is included.

Bommer – Hospital 6 is not the highest one in this group.

Aryana – Discussed the Transfer costs from hospital

Bommer – So that completes some of the data matrix and utilization matrix. I just want to review a couple things: It came up earlier that we were attempting to get NCDR data set

from all of California to compare with onsite surgery to compare with our off site surgery group. Originally when I presented this slide last time, the price from NCDR was $105,000. We went back and negotiated with NCDR and we had it reduced to $50,000 in a one on one meeting. It has to be approved by the committee or recommended because DPH reviews each expense we have and they have to approve every line item expense. So, if we go with this, because it was not on the original contract, it must be approved and DPH must go along with that. Currently, what we are doing in the absence of that, we are looking at PDD data, Patient Discharge Data and that is every hospital in California where we have that data. It actually comes to us for free, and we process that information for free. We do have those comparisons that show that we are currently similar to PDD CA data for the onsite hospitals for every hospital the NCDR would be a select group of 90 of134 hospitals. To get that information it would cost us $50,000. With this, I presented at the ACC meeting in CA last Saturday, and what we presented there was an authorization by the CA ACC to go ahead and encourage voluntary reporting of hospitals in CA. If we had that voluntary reporting in CA through ACC, we could get that data for voluntary reporting and include that, but remember that is a very select group that voluntary reports to ACC and we can get that information for no cost. The next level up is the NCDR de-identified data. Or we can go ahead and stay with the PDD data which is every hospital in CA, it does not have all the NCDR 220 fields that are included in our data set and does not allow the same level of risk adjustment that we have in our clinical data set. Brindis – Are you looking for a motion? Someone else will have to make the motion, I have a conflict. Smith – How much difference is there between utilizing the administrative data? Itchhaporia – There is a huge difference between the clinical data and the administrative data sets from the things I've seen. I think there is a big difference. Brindis – I can comment on that. The administrative data sets have real value, but the difference between clinical data sets and administrative data sets is huge when it comes to risk adjustment. Bommer- I showed data at the ACC meeting on Saturday that the correlation between administrative data sets and clinical data sets in the trials that have been published varies anywhere	

from .1 - .6 are the correlation coefficient, showing in general what we would call poor correlation, but there is correlation between those two. Those are previously published papers comparing clinical data sets with administrative data sets. What we don't have is the patient discharge data set correlation. The PDD does have a relatively crude risk adjustment associated with it. They do look at age and gender and some CPT codes for making their risk adjustments. It may be a little more adjusted than the typical administrative data set, but as we said earlier, there are maybe only a limited number of variables in the administrative data set, typically not audited and it does not compare with the NCDR data set that we're using as well as our auditing of those issues. Remember that in option number one, if we get that data from the other hospitals in CA, we're still not auditing those other hospitals. The data would come to us de-identified so each hospital does a harvest every three months and sends their information into NCDR and then NCDR will go through processing it and then they will go through and delineate the identity in about twenty fields and then they send the information to us. It comes to us where we do not know the patient ID or the information related to that and we do not know the hospital, but we will have a mask on the hospital so we can tell approximately let's say 200 patients were done at this hospital and this hospital will have a letter code to identify that. But, we will have the volume and the risk modifiers we can use the same risk model that we're using in our population, but now it would incorporate all of the reporting hospitals to NCDR which we currently feel is about 90 or 91 hospitals in CA reporting to us and we would add our six and we would have a data set of about 96 or 97 hospitals. Itchhaporia – I think option one. If we're going to do this, it would be nice to have the NCDR data from the beginning. I think the clinical data base is important so I will put as a motion that we should obtain the NCDR data base. Sundrani – I'll second that motion. Way – So we have a motion that has been made and seconded, is there any further discussion or questions? Do we want to have a call for the vote? Fehrenbacher – Would we be mandated to go back to our hospital to get the money? Bommer – The mechanism from our part would be, we would literally sign the contract with NCDR for this and we would make sure everything we needed on it was included. We would then	

invoice the Department of Public Health $50,000 for that payment. We would advance the payment, but we would also send an invoice to DPH to pay that and then DPH has their own mechanism for assessing or allocating these charges to the individual hospitals. That's why the contract each pilot hospital has with DPH. I can ask Tony to address that. Way – I looked at the original material that was generated by each of your hospitals for contracting with us on the project and on average it's six, 4" binders full of material. I need to go through that to find that particular line item because I wasn't aware of this until now. Bommer – This is not currently a line item on the contracts so it's up to DPH how they would then assess this. It being not defined until this motion, if it were to be passed, and is approved. Fehrenbacher – Taking a step further, I'm a physician at a hospital, not an administrator. The world has not become a kinder or gentler place for doctors. I, from a quality stand point, am behind it 100%, but I don't know if I can commit a hospital to expense something like that without discussing it with them first. I'm conflicted in that way. Brindis – Can I ask about option 4? Rather than looking at direct comparisons between the CA pilots with the CA hospitals utilize the overall NCDR national data and what would the downsides, from your prospective be? Bommer – As I presented today, most of those numbers from CA and obviously we could approach them and get that information. I'm going to ask Dr. Li the question of, when we do a statistical analysis of our data set versus theirs, if we have only their median number and their 25^{th} – 75^{th} percentile numbers, and we have all of our individual data, can we compare individual data with median numbers from another data set and get a statistical analysis? Dr. Li – I think that from a risk adjustment perspective, when we have a median you've lost a lot of the information in the variations. Number one is of course a good choice because the best thing about the NCDR data is the clinical information being available to make a good risk adjustment. But, if we do not have that money available, let's see if we have a volunteer program that can submit data. Brindis – I don't see how you would have 90 or 91 hospitals	

participate.

Bommer – The CA ACC did approve going ahead with voluntary reporting and we had some hospitals saying they were interested. It wasn't overwhelming right away and it will probably be less than 50% of the hospitals that will sign up for that. That is clearly going to be more limited. I did also explore mandatory reporting in CA and I have legal opinion that to get mandatory reporting, because we can get that through OSHPD, it will require when we have an attorney review those papers, that there be new legislation in CA to do that, and to do that it means we have to meet with legislators and have it approved. The earliest we could get a bill on would be in a year and it would literally be by year three of the program, we might expect mandatory reporting of that CA data.

Fehrenbacher - I have some concerns about the voluntary reporting. My suspicion is that there is going to be a significant bias selection in who reports and who doesn't.

Smith – I like Dipti's motion.

Way – So, the motion is still on the floor. I don't understand the mechanics of how this is going to occur. The state of California is broke and I don't think I (or CDPH) can obligate the state of California for any financial obligation even if it is temporary and immediately reimburse. But that said, if it can be done through our legal department and us, I'm happy to support it.

Fehrenbacher – Is it possible to amend the motion and to suggest that each individual investigator from each hospital go back to their hospital and see if they can get $1/6^{th}$ of the $50,000? If that's the case, the whole concept of your going through six binders would be moot. If each hospital voluntarily agreed to pony up the money, that would make it easier.

Itchhaporia – I'm happy to amend my initial motion in that we should do option one and we should go back to the six participating hospitals and they would have to divvy up the cost of that $50,000.

Fehrenbacher – Look, this is a trivial amount of money and what it does for these hospitals, it allows them to do more PCIs, which makes them more money. It would be crazy for them to ever even whisper a disagreement about this.

Motion - Itchhaporia – I propose that we go with option one, which would say that we are going to purchase the NCDR data base at the cost of $50,000, but that the cost be picked up by the six hospitals that are participating in the PCI pilot project.

- Karmarkar- Second
- 8 votes for, 1 abstain, the motion passes

Bommer – Summary of presentation. We are now to a conclusion part here and I am going to show you three summary slides that will review some of the aspects of the presentation that we've had today. We are on slide 78. What we've seen from the PCI campus project so far, is that in the first ten months of operation, we've had 1,039 patients enrolled, so we are running close for the total that we had projected as our minimum number per year. We have done 1,030 initial audits. 496 cases have been reviewed, adjuidicated, and gone through the entire process and are locked down for 2010 and that data will not change. We did 208 onsite audits and 269 angio audits were done as well. We have an average enrollment rate per hospital of 174 at this point with a range of 77 to a high of 318 cases in the first ten months. We have observed mortality that I've shown here that basically in the first five months the total mortality from PCI of 1.9% STEMIs were 2.29% and NON-STEMIs were 3.6% and electives were 0%. For ten months, you can see that our total mortality has slightly increased to 2.6%. Our STEMI mortality has increased to 4.25%. Our NON-STEMI has slightly dropped to 3.11%. And our elective mortality is still remaining at 0% for the first ten months. On slide 79, summary two, you can see the success rate remains high at 90% success rate for reducing or opening up the vessel with less than 20% residual stenosis, both at five and ten months. Our post procedure TIMI flow was 95% was seen at five and ten months, so it remains with a high level of TIMI flow which is wide normal flow in the coronary artery. Looking at the mortality risk model adjustment, you can see that traditional risk model adjustment, which is the first analysis that was done; there were no outliers at five or ten months. Using a more sensitive approach which we discussed here, the Funnel Risk Model Adjustment Method showed us that at five months for the lockdown data, there was one hospital that made it a worse outlier, using the 95% confidence intervals or markers at that point. At ten months, one hospital was identified in the Funnel Method as being better than the rest of the group. Significantly better than the rest of the group. And one hospital was identified as being worse than the rest of the group at the PCI Campus trial. The comparison

with the PDD data set for non-pilot hospitals, as we remarked earlier, showed no difference between CA non-pilot hospitals and pilot PCI hospitals in this trial using the clinical versus the administrative data sets. Lastly, in summary three, which is slide number 80 in your slide deck, would be what measures what we'll call appropriateness. If we look at where we are within the 25th – 75th percentile of the NCDR data set last released as the 2010 q3 data set, we can see that areas that we are measuring that are within the 25th – 75th percentile include those with a positive stress test who are going for PCI, a door to balloon time, a percent of door to balloon time, those on lipid lowering agents, vascular injury, a small number had kidney injury and are consistent with the NCDR data set, length of stay for STEMIs also within that data set, Creatine assessment pre and post PCI. Biomarkers are assessed after PCI, before and post procedure myocardial infarction. All of those areas are data that would suggest that we are similar to the NCDR data set and we are within or close to the median and within the 25th – 75th percentile. For items that were outside of that, and in this case that means we are slightly outlying this group, in this situation where we were not better, but slightly worse, that would be use of aspirin, use of thienopyridines, documenting it in the data set. And it would be the number of patients that needed to go to emergency CABG, which was higher than the NCDR data set. The number requiring transfusion, the number receiving post-procedure stroke, the number composite who were dead, CABG, or stroke, was higher than in the NCDR data set and the length of stay for individuals who did not have a STEMI. In each of those areas, we are outside the 25th – 75th percentiles. Now, remember that is not to standard deviations, it means that we are above the mean for NCDR and we are in the outer 25th percentile for that group. Brindis – I might suggest reformatting this slide because I think what you have on this slide has mixed performance measures, clinical outcomes, and performance matrix, along with appropriateness. You have four topics explained under the title of appropriateness. I think that an outsider looking at this might misunderstand. I would separate them under new slides and titles. The other challenge that we have, related to some of the clinical outcomes that were the outsiders, in that they're not risk adjusted for the acuity of patients. So, although I find the data important, it could also be misinterpreted knowing that we have a higher STEMI rate than the general population with higher risk. Bommer – Number one, I can remove appropriateness right now. And there's the new slide. So, there are your summary	

three slides, ok? We'll come up with a title that lists each of those. I listed it earlier when I went through the NCDR sets for each one and I had those definitions, but it just seemed pretty cluttered to get every one of those definitions on which is why I left those off. Fehrenbacher – I would like to emphasize that mixing up risk adjustment and risk of death outcomes is very confusing to non-cardiologists. Bommer – So, one of the reasons for presenting this was at the last meeting we talked about appropriateness, so what I wanted to include here was some of the measures that we could look at, etc. Now, the difficulty is if we look at every one of these things and do a risk adjustment model, this is a fairly large amount of analysis from a large group of patients to do, so what he's asking for is, are there some of these that might be added, because we've looked at mortality, CABG and the high risk of morbidity and mortality. We want to add some of these quality metrics and areas of performance. Is there a limited number we could pick to do risk adjustment for? Because if we do risk adjustment for every one of these, you'll have so much data at the next meeting that we'll have to schedule cots in here to go through all that data. Fehrenbacher– I guess I would say that the outcomes, we're already risk adjusting death. We're not risk adjusting CABG, is that correct? Bommer – CABG is very few. Fehrenbacher – I think that death, CABG and stroke are the three big ones. For someone to say that we have a higher stroke rate, I would argue that it is dependent on the patient population so that the transfusion is less important. Bommer – The difficulty is, we don't have for risk adjustment, NCDR does not risk adjust these parameters. What we're doing is comparing apples to apples. This is NCDR's median at 25th – 75th percentile and NCDR does not risk adjust for those. If we risk adjust for it, then we will have a somewhat different data set than NCDR at that point. Fehrenbacher – I'm wondering if it's important. I don't think transfusions are important, but transfusions related to vascular complications are important. I think things that are related to the acuity of the patient and are not risk adjusted by NCDR, I find not particularly useful.	

Brindis – I agree with half of what you said. Transfusions are very important. They increased length of stay, mortality, and there is a lot of data on that. The issue is related to the risk adjusting acuity of the patient. Bommer – One of the difficulties in risk adjustment, say for GI bleed non-PCI related is, we don't include those markers in the current data sets, so we don't really know who has had cancer, who has had an ulcer, who has had gastritis, because it's not in our data set at all. The only thing we can risk adjust it for, is their age, gender, and that may not pick up what you're looking for. Fehrenbacher – I'm suggesting that transfusion is not as important in this context, unless it is risk adjusted for the acuity of the patient. Karmarkar – I appreciate the discussion. I can see both sides of the issue. Some of the things that are not under our control or the data is not available from NCDR, but the two things that are completely under our control is aspirin and clopidogrel on discharge. That should be 100%. I'm wondering if some of this is related to coding or picking up the data. I'm not being naïve or being in denial, we are electronic medical records, but we go by order sets. Part of order sets is that you have to check off aspirin and clopidogrel, after PCI. If you don't, you can't even sign the order set unless you give a reason why you're not giving aspirin, clopidogrel, or statin, or beta blockers, etc., so the cardiac quintet is included in the order set. You cannot complete the order set unless you check this off, so I'm surprised that it's not 100%. Smith – We've looked at in our hospital and looked at possible voluntary reporting and what we found is that it was incomplete data entry. If you don't put it in, it didn't happen. Bommer – I think that's one of the advantages, let's say, looking at this data is that this could be "tools" for the individual hospitals to go back and look at how to improve the reporting of this. The reason I have presented here is that we previously had not used this data or audited it, so it's possible that hospitals under reported it and didn't worry about it. I think now, with this, we can give this as a tool to the hospital and say work with this and their coders to make sure that is there because I agree that after a stent, you probably should be on aspirin and anti-platelet therapy unless it's contra indicated. We can use this as tools for the hospitals to try to improve their	

care so their overall outcome, which is still mortality, is the primary outcome we're studying here. This is just another tool for the hospitals to fine tune. Fehrenbacher – We can go back to our coders to achieve a better rate. It is totally dependent of the acuity of the patient. Can we change it? Bommer – I changed the slide, Appropriateness disappeared. Would you be interested in the PCI Campus, our giving this to your hospital and to primary investigator to look at? They can make sure they are coding it in, and make sure they aren't missing out on patients. Fehrenbacher – We do look at it. We have the NCDR data, we have quarterly reports. Does this PCI CAMPOS have additional quality improvement vehicle over the NCDR quarterly reports? Brindis – I would hope so; we have spent the day going over it. There is no doubt that it has higher level of data and quality assessment. Way – As a non-cardiologist, if someone gave me this data and we fell out of the 25th – 75th percentile range, it would say that I must be doing something wrong, or at least need to be looked at seriously. Bommer – I think it would be nice if the PCI campuses are showing that it is as safe and effective to do PCI at hospitals without onsite surgery. That is it would be nice if we got close to the NCDR numbers on that. Brindis – The take home message I get is 1.) Is Bill, your team does a great job of letting this committee do its job. 2.) You look at the last slide, it says we have a problem, I don't know if we have a problem. Bommer – It turns out our Stroke and CABG rate is higher than NCDR. When we combine the three together we get that. Mortality is not. Fehrenbacher – Risk adjustment is extremely important here. If we compare ourselves to the average California hospital doing a lot of outpatient angioplasties without risk adjustment we are going to look poorly, based on our acuity. Bommer – The risk adjustment that we are doing is only within our six hospitals. We don't have access to the NCDR data or the	

California data. Fehrenbacher – The lack of risk adjustment for all those variables is interesting, but it doesn't tell the whole story. Jain – I was wondering the low volume of patients compared to the NCDR data, does that make a difference? Bommer – The smaller the number the more likelihood that a random chance could lead to the discrepancy and that it would not be performance but a random variation. Bommer – Are there items that you want to pick here that we would, from the list I showed you, that you would want to include in risk adjustment within the PCI campus model system? Fehrenbacher – Would it be possible to risk adjust emergent coronary artery bypass surgery? That is the main issue that differentiates us from surgical site hospitals. Bommer – It will be a somewhat limited number, we had 12 patients but we can analyze and process that. Li – I propose that we for the next meeting, risk adjusted compulsive covers death, CABG and death. Bommer – I think that concludes my presentation if there are no other questions. Fehrenbacher – Rotational atherectomy should be included in the study. Bommer – We will reread the bill, I don't have a problem as long as the operators that do it, are appropriately trained and credentialed. Fehrenbacher – The 15 lbs. of papers we had to sign it was precluded. Bommer – I didn't see those papers, but it wasn't in the bill. We can take a vote, would you like to make a motion? **Motion – Fehrenbacher – Rotational Atherectomy in properly selected cases is permitted in the PCI pilot project with appropriately trained and credentialed operators.** ➢ Second – Sundrani	

➢ Motion passed by unanimous vote Karmarkar – Is there a certain percentage of review of PCIs mandated in bill. Is anyone doing review of every PCI? Fehrenbacher – We are not. Arnold – It falls within our quality review process. Jain – We are reviewing all PCIs, I want to make sure they are coded right. But, not required by the institute. Way – Action items, Dr. Bommer and Carrie Camarena will work on their item and explore. It will come back as an item for your review and if action needs to be taken, we would have to schedule a meeting. I talked to Dr. Bommer when data will be completed and that would be in January and he has given me dates for the next meeting. **Motion – Arnold - Next meeting will be Thursday, January 19, 2012.** ➢ Second – Brindis ➢ Passed by unanimous vote Bommer - I have to caution you about the Bagley-Keene issue that you can't meet and discuss among yourselves with regards to items and issues that come before this committee. 13:55 - Meeting Adjourned	

Acronyms

ACC	American College of Cardiology
AFL	All-Facilities Letter

AOC	Advisory Oversight Committee
AVI	Audio Video Interleave
CA	California
CABG	Coronary artery bypass graft
CAMPOS	California Audit Monitored Pilot with Offsite Surgery
CDC	Centers for Disease Control and Prevention
DPH	California Department of Public Health
CMS	Centers for Medicare and Medicaid Services
CQI	Continuous quality improvement
CT surgery	Cardiothoracic surgery
EKG	Electrocardiogram
FFR	Fractional Flow Reserve
HIPAA	Federal Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MI	Myocardial Infarction
NCDR	National Cardiovascular Data Registry
Non-STEMI	Non-ST Elevation Myocardial Infarction
OLS	DPH Office of Legal Services
OSHPD	Office of Statewide Health Planning and Development
OR	Operating Room
PCI	Percutaneous Coronary Intervention
PDD	Patient Discharge Data
RCA	Right coronary artery
RAMR	Risk adjusted mortality rate
SCAI	Society for Cardiac Angiography and Interventions
STEMI	ST-Elevation Myocardial Infarction
STS	Society of Thoracic Surgeons
TIMI	Thrombolysis in Myocardial Infarction
UCD	University of California at Davis